

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the reasons which follow.

The examiner's basic concerns revolve around the Buckley reference which, as applicants have shown below, does not anticipate the present invention because the Buckley reference does not teach antigens of the same molecular weights as the antigens disclosed in the present invention. The claim amendments set forth in this response place the application in condition for allowance by clarifying the subject matter of the invention and correcting errors in spelling and claim structure. Therefore, applicants request that the examiner enter these amendments and allow these claims.

Claims 18-37 are pending in this application. Claims 23-30 were amended to comport with USPTO patent drafting procedures and to correct errors in spelling. Additionally, the examiner requested further description for the numbers 55 kDa, 30 kDa, and 20 kDa. From the rejections in the previous office action, it appears that the examiner correctly assumed that these numbers represent the antigens "molecular weight." However, for clarification, claim 37 was amended to describe 55 kDa, 30 kDa, and 20 kDa as representing the "molecular weight" of the antigens.

### **35 U.C.S. §112, second paragraph**

Claims 24-29, 37 are rejected under 35 USC 112 for not distinctly claiming the subject matter of the invention. As stated above, the claims have been amended to overcome this rejection. Specifically, claims 24-29 have been amended to properly recite their Markush groups. Further, claim 37 has been amended to specify "molecular weight" before providing the antigens' weight of 55 kDa, 30 kDa, and 20 kDa. Applicants argue that the application is in condition for allowance because the subject matter of the invention is distinctly claimed.

### **35 U.C.S. §102**

The examiner has rejected claims 18-34 as being anticipated by Buckley *et al.* (U.S. 4,806,465). The examiner found that Buckley discloses a method of diagnosing *Candida* infection, comprising the steps of:

- a) obtaining a biological sample from a subject
- b) preparing an antigen composition comprising a soluble cytoplasmic antigen preparation

which is mannose depleted (claims 1-4, column 4 lines 21-26)

c) contacting said antigen with said biological sample

d) using a detection system to determine if antibodies from the sample are bound to said antigen composition.

Applicants disagree that the Buckley reference describes antigens extracted from both the mycelia or yeast form of *Candida*. Even though the Buckley reference mentions on column 4, lines 21-25 that “the mannan-depleted cytoplasmic extract of mycelia or yeast is fractionated by ion exchange chromatography...,” the reference as a whole teaches the preparation of antigens predominantly from the mycelia form. For example, the methods used for the antigen preparation describe the cells “grown under these conditions as 90% mycelium and 10% yeast cells.” Further, Buckley describes the solution as “the mycelial-phase cytoplasmic extract (MCE)” rather than the yeast-phase cytoplasmic extract. Buckley, therefore, states that the predominant material used for the cytoplasmic antigen preparation was the mycelium form *not* the blastospore form.

Because Buckley used the mycelial-phase cytoplasmic extract and did not teach using predominantly the blastospore-phase cytoplasmic extract, the antigen preparation of the Buckley reference and the antigen preparation of the present application are different. Therefore, the present invention is novel and inventive over Buckley *et al.*

Additionally, contrary to the examiner’s contentions, the antigens obtained by the Buckley method and the present application’s method have different molecular weights and thus, cannot be the same antigen. The examiner contends that Buckley teaches multiple antigens including ones maintaining molecular weights of 55 kDa (figure 6 and 7), 30 kDa (figure 3), and 20 kDa (figure 3). However, applicants respectfully submit that neither the figures nor the legends (columns 15 and 16) support this contention. Although column 15 lines 20-36 refers to figure 3, it does not describe the sizes of the antigens shown. Additionally, column 12 describes figure 3 as showing antigens with “an apparent molecular weight of 48-52 Kd. Further, the legends for figures 6 and 7 (column 15, line 66 to column 16, line 14) each refer to a 48 Kd (figure 6) or “the three antigens (the 48 to 52 Kd protein, the 120-135 Kd, and the 35-38Kd protein).” Finally, after reviewing the Buckley reference, applicants argue that this reference does not describe a 55 kDa, 30 kDa, or 20 kDa antigen. In fact, throughout the Buckley reference, the patent refers to antigens having molecular weights of 120 to 135 Kd, 48-52 Kd, and 35-38 Kd (see abstract lines 5-6, column 3, lines 21-22, and 65-66; column 4,

line 5; column 12, lines 34-38; column 13, line 68; column 14, line 26; and column 16 lines 64-66). Therefore, because the Buckley reference does not disclose antigens with the same molecular weight as the antigens disclosed in the present application, the Buckley reference does not anticipate the present invention.

Finally, applicants append a statutory declaration by Professor Warmington showing that the monoclonal antibodies used by Buckley *et al.* to identify the antigens disclosed in the Buckley reference do not cross react with the presently claimed antigens. Because the monoclonal antibodies disclosed in the Buckley reference react with the Buckley antigens but fail to react with the present invention's antigens, these antigens cannot be the same and hence, cannot anticipate the present invention.

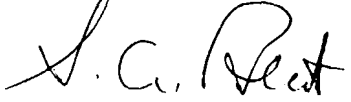
### CONCLUSION

Based on the foregoing, applicants submit that the present application now is in condition for allowance, and a timely indication to this effect is respectfully requested. Examiner Shahn Shah is invited to contact the undersigned directly, should he feel that a telephone interview would advance the prosecution of this application.

3 November 2003  
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Respectfully submitted,

  
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**Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.**